

What Is Claimed Is:

1. Apparatus for removing emboli during an angioplasty or stenting procedure, the apparatus comprising:

a catheter having proximal and distal ends, a lumen extending therethrough, and a blood outlet port in communication with the lumen, the catheter adapted to be disposed in a patient's carotid artery;

an occlusion element disposed on the distal end of the catheter and having an opening that communicates with the lumen, the occlusion element having a contracted state suitable for transluminal insertion and an expanded state wherein the occlusion element occludes antegrade flow in the vessel;

a venous return catheter having proximal and distal ends, a lumen extending therethrough, and a blood inlet port in communication with the lumen; and

tubing that couples the blood outlet port to the blood inlet port.

2. The apparatus of claim 1 further comprising a wire having a distal end and a balloon disposed on the distal end, wherein the wire and balloon are sized to pass through the lumen of the catheter.

3. The apparatus of claim 1 further comprising a blood filter coupled between the blood outlet port and the blood inlet port.

09591417-11601

4. The apparatus of claim 1 wherein the occlusion element is an inflatable member.

5. The apparatus of claim 4 wherein the inflatable element has a pear-shape with a wall thickness that varies along the length of the inflatable member.

6. The apparatus of claim 4 wherein a portion of the pear-shaped inflatable member extends beyond the distal end of the catheter in the contracted position and forms an atraumatic bumper.

7. The apparatus of claim 1 wherein the occlusion element comprises a self-expanding basket.

8. The apparatus of claim 1 wherein the catheter comprises:

- a non-stick tubular member;
- a layer of wire braid disposed surrounding the non-stick tubular member; and
- a layer of thermoplastic polymer disposed on the layer of wire braid.

9. The apparatus of claim 1 wherein the catheter further comprises a second lumen through which the wire and inflatable balloon may be inserted.

09991417 "11601

10. The apparatus of claim 1 further comprising a pump that removes blood through the catheter and reperfuses blood via the venous return catheter.

11. The apparatus of claim 2 further comprising a resilient wedge affixed to the wire proximal of the balloon to reduce snagging of the balloon following a stenting procedure.

12. A method for removing emboli from a vessel comprising:

providing a catheter having proximal and distal ends, a lumen extending therethrough, an occlusion element disposed on the distal end, a hemostatic port coupled to the lumen, and a blood outlet port coupled to the lumen;

providing a venous return catheter having proximal and distal ends, a lumen extending therethrough, and a blood inlet port coupled to the lumen;

inserting the distal end of the catheter to a position proximal to the stenosis;

inserting the distal end of the venous return catheter into a remote vein;

deploying the occlusion element to occlude antegrade flow through the vessel;

05991417 " 11601

causing blood to flow between the blood outlet port and the blood inlet port to induce reverse flow in, and remove emboli from, the vessel.

13. The method of claim 12 further comprising:

providing a blood filter; and
coupling the blood filter in fluid communication between the blood outlet port and the blood inlet port.

14. The method of claim 12 further comprising:

providing a wire having a balloon;
while flow is reversed in the vessel,
advancing the balloon of the wire into the patient's external carotid artery;
inflating the balloon of the wire to prevent reverse flow from the external carotid artery from entering the internal carotid artery.

15. The method of claim 12 further comprising, while causing blood to flow between the blood outlet port and the blood inlet port, performing an interventional procedure with an interventional instrument inserted through the hemostatic port.

09991417 111604

16. The method of claim 12 wherein the occlusion element comprises a balloon, and deploying the occlusion element comprises inflating the balloon.

17. The method of claim 12 wherein the occlusion element comprises a self-expanding basket, and deploying the occlusion element comprises retracting a sheath relative to the distal end of the catheter.

18. The method of claim 14 wherein advancing the balloon of the wire into the patient's external carotid artery comprises advancing the balloon through a separate lumen of the catheter.

19. The method of claim 12 further comprising:

providing a pump; and

actuating the pump to increase a rate of flow of blood between the blood outlet port and the blood inlet port.

20. The method of claim 15 wherein performing an interventional procedure with an interventional instrument comprises delivering a stent within the vessel and the wire further comprises a resilient wedge, the method further comprising urging the resilient wedge against the stent during removal of the wire and balloon.

099447-1104